September 15, 2021

Vascular Solutions, Inc.
Julie Tapper
Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, Minnesota 55369

Re: K063371
Trade/Device Name: Pronto V3 Extraction Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ

Dear Julie Tapper:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 14, 2006. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2021.09.15 09:24:12 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 14 2006

Vascular Solutions, Inc.
c/o Ms. Julie Tapper
Regulatory Affairs Associate
6464 Sycamore Court North
Minneapolis, MN 55369

Re: K063371
Pronto™ V3 Extraction Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Catheter, Embolectomy
Regulatory Class: II (two)
Product Code: DXE
Dated: November 6, 2006
Received: November 8, 2006

Dear Ms. Tapper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vachney

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K063371

Device Name:
Pronto™ V3 Extraction Catheter

Indications for Use:
The Pronto catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Kochner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K063371

DEC 14 2006

510(k) Summary

(As required by 21 CFR 807.92(c))

510(k) Number: K063371

Date Prepared

November 29, 2006

Submitter Information

Submitter's Name:	Vascular Solutions, Inc.
Address:	6464 Sycamore Court Minneapolis, MN 55369
Contact Person:	Julie Tapper Regulatory Affairs Associate Phone 763-656-4228 Fax 763-656-4253

Device Information

Trade Name:	Pronto™ V3 Extraction Catheter
Common Name:	Embolectomy catheter
Class:	II
Classification Name:	Embolectomy catheter (21CFR870.5150, Product Code DXE)

Predicate Devices

Pronto™ V3 Extraction Catheter (K052232), manufactured by Vascular Solutions, Inc.

Device Description

The Pronto V3 extraction catheter is a dual lumen polymeric catheter that is reinforced with a braided metallic mid-layer. The Pronto V3 includes related accessories. The extraction lumen allows for the aspiration and removal of embolic material (thrombus/debris) by using the included syringe, extension line and stopcock. The catheter has a rounded distal tip with a protected, sloped opening of the extraction lumen that facilitates atraumatic advancement of the catheter into the blood vessel and maximizes the extraction of emboli/thrombi through the extraction lumen. Near the catheter's distal tip is a non-blood contacting radiopaque marker for fluoroscopic visualization.

The catheter has a monorail design. It has a flexible distal region and stiffness along the shaft and proximal region. The proximal end of the catheter has a standard luer adapter that attaches to the included extension line, stopcock, and syringe. The distal region of the catheter has a lubricious hydrophilic coating that allows for ease of catheter advancement. The catheter has an approximate outer diameter of 0.065 inches, allowing for delivery through standard 6F guide catheters. The guide wire lumen of the catheter accommodates guide wires that are $\leq 0.014''$ in diameter. The catheter has a working length of 140 cm. To facilitate laboratory analysis of the thrombus, a filter basket is included for filtering the blood from the thrombus.

Intended Use/Indications for Use

The Pronto catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature.

Summary of Testing

No additional testing was required to support this indication.

Statement of Equivalence

The Pronto V3 catheter is substantially equivalent to the currently marketed Pronto V3 catheter, based on comparisons of the device classifications, indications for use, technological characteristics, thrombotic or embolic material-removal methods, and sterilization methods.

Conclusion

The Pronto V3 extraction catheter is substantially equivalent to the currently marketed Pronto V3 catheter, based on comparisons of the device classifications, indications for use, technological characteristics, thrombotic or embolic material-removal methods, and sterilization methods.